

REMARKS:

In the Advisory Action mailed February 14, 2003, indication is given that the proposed amendment of November 25, 2002, would not be entered because it raises new issues. The indication is that those new issues concern the insertion of the language "one of the" and the recitation "of long-term disease progression". The comments in Paragraph 10 suggest that a computerized physiologic model has not been set forth in the claims. The comments further restate the characterization of Thompson and Nappholz as inherently disclosing "some type of comparison to a physiologic model in order to change parameters."

By this response, the basis for the alleged "new issues" has been removed from the claims. Additionally, the claims now clearly recite computerized control of an implantable medical device using a computer resource including a physiologic model.

In the Final Rejection, Claims 1-9, 12, 14 and 15 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,083,248 to Thompson et al. (Thompson). Thompson is characterized as acquiring data from an implantable medical device for transmission to a centralized computing resource. Further, Thompson is deemed to inherently compare acquired data to a model. Alternatively, Thompson is characterized as disclosing the claimed invention except for analyzing data according to a physiological model. The Final Rejection then relied upon Scarantino (U.S. Patent No. 6,402,689) as disclosing the analysis of physiological data according to a physiologic model.

Claims 1-9 and 12 were also rejected as obvious under 35 U.S.C. §103(a) over U.S. Patent No. 5,720,770 to Nappholz et al. (Nappholz) in view of Thompson. Nappholz was considered to inherently disclose analyzing physiological data according to a suitable model.

Claims 10 and 19 were rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,186,170 to Varrichio et al. (Varrichio). Claims 11 was rejected under 35 U.S.C. §103(a) over Thompson (or Nappholz) in further view of U.S. Patent No. 5,899,931 to Deschamp et al.

(Deschamp). Claims 16-18 stand rejected under 35 U.S.C. §102(b) or alternatively as obvious under 35 U.S.C. §103(a) over Nappholz.

Claim 13 was rejected under 35 U.S.C. §112, first paragraph. Claim 13 was been cancelled.

A. Claim Rejections Based on Thompson and Nappholz

The rejection of claims 1 and 14 on either Thompson or Nappholz is premised on an alleged inherent disclosure that physiological data is analyzed according to a physiologic model. In the alternative, Scarantino is relied upon. The limitation at issue is being construed to mean that a comparison of the acquired data is made to a model. No indication is given as to a specific disclosure in any of the references as to how persons of ordinary skill in the art would recognize that the analysis in Thompson or Nappholz is a comparison of data to a model. The change in parameters by the medical support staff is more likely made on the basis of an indication that one item of data indicates operation of the implantable medical device in a manner in consistent with the desired operation, which does not implicate a "physiologic model."

In Thompson, at the remote medical support center, a medical support staff reads telemetry from the implantable medical device and reprograms its operation. See col. 6, lines 2-5. There clearly is no indication of a comparison of acquired data to a physiologic model. Instead, the indication is that a medical staff member reviews the data and provides the instructions transmitted to the implantable medical device for reprogramming its operation.

In Nappholz, the repeater programmer provides communication to a remote center where a physician reviews the device data and enters instructions for changing the device functional parameters. See col. 7, lines 59-60. Again, there clearly is no indication of a comparison of acquired data to a physiological model.

Finally, in Scarantino, the status of a tumor undergoing treatment is monitored by tracking of parameters relating to the tumor in evaluation of a treatment strategy. Data transmission from a non-clinical site to a physician interface is provided. Scarantino describes that the evaluation includes

determining whether treatment is progressing according to a "predictive model" (col. 13, lines 20-22). The evaluation in Scarantino is described as being based on the deviation of the tumor's response to the delivered therapy at a particular point in time as measured against a population norm.

As pointed out above, neither Thompson nor Nappholz expressly indicates that a physiologic model is involved at all. The characterization of Thompson and Nappholz as inherently including a model is speculative and unsupported. That comparison to a model may result or could result is insufficient as inherency cannot be established by possibilities or even probabilities. See, *In re Robertson*, 169 f.3d 743, 745 (Fed. Cir. 1999). Moreover, if the sole basis for an obviousness determination rests on a defective finding of anticipation, then the obviousness determination will fall as well. *Id.*

As for a rejection of obviousness based on a combination of either Thompson or Nappholz and Scarantino, there is no indication of the required showing of a suggestion to combine the references. *In re Dembiczak*, 175 F. 3d 994 (Fed. Cir. 1999). Where there is a failure, as here, to cite specific information in the prior art that would suggest the combination of the prior art references, the rejection is improper as a matter of law. *Id.*

Furthermore, there would be no basis to include a predictive model in either Thompson or Nappholz. Each of Thompson and Nappholz are clear that a medical support staff reviews the acquired implanted medical device data and provides instructions for reprogramming the device. There is no reason to forecast disease progression, which is what Scarantino is attempting to do.

Yet further, Scarantino cannot be regarded as being within the scope and content of the prior art relevant to the claimed subject matter. To be properly within the scope and content of the relevant prior art, a reference must be reasonably pertinent to the particular problem involved. That is, the prior art must be within the inventor's particular field of endeavor and any analogous art. *Markman v. Lehman*, 987 Fed. Supp. 25, 29 (D.D.C. 1997), *aff'd*, 178 F.3d 1306 (Fed. Cir. 1998). The present invention concerns control of an implantable medical device that delivers therapy to a patient. In Scarantino, a sensor unit is

implanted in a patient to monitor a parameter concerning the condition of a tumor. The sensor unit in Scarantino does not concern an implantable medical device delivering therapy to a patient.

Finally, the claims now specify computerized control of an implantable medical device deployed in a patient. The claims specify that a central computing resource accessible by a data communication network and including a physiologic model is operable to (a) analyze a set of patient data recorded by the implantable medical device and transmitted via the data communication network using the physiologic model, and (b) make a computerized determination of a set of instructions comprising an implantable medical device therapy regimen based on the set of results from the analysis of the set of historical physiologic data. Then such set of results can be transmitted via the network communication link or a separate network communication link to the implantable medical device for execution by the implantable medical device in accordance with an executable routine resident in the implantable medical device. None of the cited references disclose these features.

B. Conclusion

For the foregoing reasons, claims 1 and 14 and the claims dependent from them should be allowed.

Respectfully submitted,

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